*Remarks*

Claims 22-29, 32, 36-43 and 45-48 are pending of which claims 22-27, 36, 37 and 45-58 are rejected. Claims 28, 29, 32, 38-43 are objected to. Claims 1-21, 30-31, 33-35, and 49-54 were previously canceled. Claims 22 and 48 are amended. Following claims remain in the application for consideration: 22-29, 32, 36-43 and 45-48.

35 U.S.C. §102 (b) Rejections

(i) *Claims 22-27 and 45-48 are rejected under 35 U.S.C. §102 (b), , as being anticipated by Talwar et al (GB2236480). Applicants traverse the rejection of these claims.*

The POSITION taken in the Action in rejecting claims 22-27 and 45-48 is that tuberculosis is an obstructive lung disease and a vaccine directed to tuberculosis must also prevent obstructive lung disease ("OLD"). In other words, the Actions construes that tuberculosis is an obstructive lung disease.

At the outset, Applicants note that the claims are directed to a method of treating or managing obstructive lung disease . . ..", i.e., new method of use, which are legally patentable claims because the Federal Court, *In re Martin Gleave*, 2008-1453 (Fed. Cir. 2009), explained that "[I]f the use [] discovered is new, [one] will be able to patent that method of use [claim]" Id.

Moving to the POSITION taken in the Action, for a prior art reference to anticipate a patent, it must disclose each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). In *Zenith Electronics Corp. v. PDI Communication Systems, Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008), this court held that "anticipation cannot be proved by merely establishing that one 'practices the prior art." Instead, "[a]nticipation requires a showing that each element of the claim at issue, properly construed, is found in a single prior art reference. 'It is the presence of the prior art and its relationship to the claim language that matters for invalidity.'" Id. (quoting *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357 (Fed. Cir. 2002)).

The element, "obstructive lung disease," recited in independent claims 1 and 48 of the instant application is neither explicitly nor inherently disclosed in Talwar because Talwar is

silent in regards to teaching a method for treating OLD. the Action's interpretation that the tuberculosis "patient populations are indistinguishable" from patients suffering from OLD is merely speculative without proof and lacks technical and scientific basis.

For a person skilled in art obstructive lung disease is a separate entity and never confused with tuberculosis because, by definition, in an obstructive lung disease, airway obstruction causes an increase in resistance. During normal breathing, the pressure volume relationship is no different from in a normal lung. However, when breathing rapidly, greater pressure is needed to overcome the resistance to flow, and the volume of each breath gets smaller. see for example paragraphs [0002]-[0029] of the PGPUB US 2007/0059328. See also **Appendix A,** also available online at http://www.medicine.mcgill.ca/physio/vlab/resp/Lungdiseases_n.htm.

In contrast, tuberculosis (TB) is a disease caused by bacterium *Mycobacterium tuberculosis*. The bacteria usually attack the lungs, but TB bacteria can attack any part of the body such as the kidney, spine, and brain. http://www.cdc.gov/TB/ **Appendix B**.

As an example that OLD should not be confused with TB, in a study "Obstructive Lung Disease and Low Lung Function in Adults in the United States" conducted on a population of 20,050 adults in the US in 2000, not a single individual was included who suffered from tuberculosis because for a person skilled in art tuberculosis patient population is distinguishable from patients suffering from OLD. According to this publication, "[O]bstructive lung diseases (OLDs), [] include chronic bronchitis, emphysema, and asthma," i.e., diseases characterized by limitation of air flow to the lungs. See *Arch Intern Med.* 2000;160:1683-1689. **Appendix C**.

In conclusion, contrary to the Examiner's assertion, patient populations for TB are clinically distinguishable from patient populations for TB.

If the Examiner believes to the contrary, evidentiary support for such assertion is respectfully requested. When an Examiner relies on a scientific theory (i.e., tuberculosis "patient populations are indistinguishable" from patients suffering from OLD), evidentiary support for

the existence and meaning of that theory must be provided. *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979).

Reiterating Gleaves, "if the use [] discovered is new, [one] will be able to patent that method of use," which is exactly what is recited in the claims of the instant application. Therefore, Applicants respectfully request that the rejection to claim 22-27 and 45-48 be withdrawn because they lack technical and legal merit.

(ii) *Dependent Claims 36 and 37 are rejected under 35 U.S.C. §103(a), as being unpatentable over Talwar et al (GB2236480). Applicants traverse the rejection of these claims.*

As set forth in the foregoing, "obstructive lung disease," recited in independent claims 1 and 48 of the instant application is neither explicitly or inherently disclosed in Talwar, therefore are patentable for the reasons discussed above.

It is well known that if an independent claim is patentable, then any claim depending therefrom cannot be obvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants respectfully request that the rejection to claims 36 and 37 be withdrawn.

*Conclusion*

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such action is hereby solicited.

A telephonic interview between the Examiner and Applicant's representative below is requested to resolve any remaining issues and answer any questions the Examiner may have. Please call the undersigned attorney at 617-345-3691 to conduct the substantive interview or briefly to arrange a time for it (or arrange by e-mail to shasan@burnslev.com).

Respectfully submitted,

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Reg. No.: 67,231

/Shahid Hasan /
Shahid Hasan, Ph.D.
Attorney for Applicant
Burns & Levinson LLP
125 Summer Street
Boston, Massachusetts 02111-1624

Tel. No.: (617) 345-3691
Fax No.: (617) 345-3299